

REMARKS

Applicants respectfully request entry of the amendment and reconsideration of the rejection of the claims.

Claims 29-56 have been cancelled without prejudice or disclaimer. These claims are cancelled as a result of a restriction requirement. Applicants reserve the right to pursue the subject matter of these claims in one or more divisional applications.

Claims 25-28 and 58-62 have been amended. Applicants have not cancelled claims 58-62 as these claims are directed to methods using a product of claims 25-28 and as such Applicants are entitled to rejoinder upon notice of allowable subject matter of any of the product claims. The amendments to the claims are supported throughout the specification including at page 9, paragraphs 0109 to 0111, and Figure 3 (referring to the published application 2004/0213801).

Claims 63-68 are new. The new claims are supported throughout the specification including in Figure 3, pages 9-11, and the examples (referring to the published application 2004/0213801).

Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 25-28 under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description. Specifically, the Examiner contends that the application is directed broadly but only describes a limited number of polypeptides, and thereby does not allegedly convey possession of the entire scope of the claims. Applicants respectfully traverse this rejection.

As noted in the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶1, “Written Description” Requirement (“the guidelines”), there is a “strong presumption” that an adequate written description of the claimed invention is present when the application is filed, 66(4) *Fed Reg.* 1099, 1105 (2001); *see also, In re Wertheim*, 191 USPQ 90,97 (CCPA 1976). The guidelines further state that “[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims.” 66(4) *Fed. Reg.* at 1107; 191 USPQ at 97, (emphasis added). The test is whether the originally filed specification reasonably conveys to a person having ordinary skill in the art that applicant had possession of the subject matter later claimed. *In re Kaslow*, 217 USPQ 1089 (Fed. Cir. 1991).

The Examiner characterizes the claimed subject matter as “peptidomimetics that are capable of forming stable coiled-coil or α -helical gp41-like structures”. Applicants are not sure if the examiner meant to characterize coiled coil structure and α -helical gp41-like structures as alternatives or to indicate the peptidomimetic can have either structure. Applicants submit that the currently pending claim 25 is directed to conjugate polypeptides that have at least two components that include amino acid sequences that may form both of these structures. Claim 25, as amended, is directed to a conjugate polypeptide formed from two or more amino acid sequences that comprise: (a) a first gp41 polypeptide having an amino acid sequence corresponding to a polypeptide comprising the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3 and is capable of forming a stable coiled-coil structure; and (b) a second gp41 polypeptide having an amino acid sequence corresponding to a polypeptide comprising the amino acid sequence of SEQ ID NO:5 or SEQ ID NO:6 and is capable of forming a stable coiled coil structure; wherein at least three polypeptides of (a) and (b) are alternately linked to one another via a bond, such as a peptide bond (amide linkage) to form the conjugate polypeptide, or at least two polypeptides of (a) and (b) are linked by an amino acid linking sequence consisting of about 2 to about 25 amino acids to form the conjugate polypeptide.

Applicants’ submit that the specification reasonably conveys to a person having ordinary skill in the art that Applicants had possession of the subject matter as claimed. Applicants have described and provided several sequences that correspond to the N terminal and C terminal helical domains of gp41. See the specification, for example, at pages 9-11. Applicants have identified the location of the heptad repeat sequence in each domain at page 9 paragraphs 0109-0111. The sequences of other gp41 polypeptides of other HIV strains are known and readily obtainable in public available databases. Thus, one of skill in the art can readily align a gp41 sequence from a HIV isolate with, for example, a N terminal amino acid sequence such as SEQ ID NO:2 or a C terminal amino acid sequence such as SEQ ID NO:5 and determine the amino acid sequence that corresponds to the reference sequence. Applicants have also made at least two conjugate polypeptides as described in the examples.

Applicants respectfully assert that the specification sufficiently describes the structures claimed in (a) and (b) of claim 25. The generalized structure required by the claims can be found throughout the specification, including detailed descriptions at page 11, lines 7-15 and at page

11, line 29 to page 12, line 11. Applicants have disclosed a multitude of sequences that produce the structures claimed in (a) and (b) of claim 25. Sequences providing the coiled-coil structure are disclosed at page 7, lines 1-6; page 11, lines 12-23; page 23, line 20 to page 26, line 10; and Tables III and IV. Sequences providing the α -helical structure corresponding to the transmembrane-proximal amphipathic α -helical segment of gp41 are disclosed at page 7, lines 7-12; page 12, lines 8-30; page 26, line 11 to page 28, line 25; and Tables I and II. These sequences provide examples of sequences that can be used to produce the claimed conjugate. Applicants respectfully assert that the specification conveys possession of the claimed subject matter.

Further, the Examiner contends that Applicants have provided a limited number of polypeptides of the limitations, but the claims encompass "an inordinate number of species that are neither described nor contemplated." Examples are not required to meet the written description requirement. *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006). Moreover, in order to have possession of members of the claimed genus, the specification need not describe all of the species that the genus encompasses. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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